REMARKS

The above-noted amendments to claims 67 and 85 are respectfully submitted in response to the official action dated December 11, 2007, herein.

Applicants submit that, in light of these amendments, as well as the terminal disclaimers submitted herewith in response to the obviousness double-patenting rejection in this case, all of the remaining objections have now been overcome, and this application is now in condition for allowance.

Claims 67, 70-76, 79-88, and 91-03 have been rejected as being unpatentable over Miranda *et al.* under 35 U.S.C. § 103(a). The Examiner contends that Miranda *et al.* teaches a transdermal comprising a drug, an acrylate polymer and a polysiloxane, and that the acrylate polymer is composed of at least 50% alkyl acrylate monomer, while butyl acrylate is disclosed therein. The drug is said to be 0.3-50% of the composition and selegiline is said to be disclosed, as is ethanol, citing column 15, line 14 thereof. The Examiner thus concludes that it would be obvious to make a composition comprising an acrylate to deliver selegiline in view of Miranda *et al.*, and that as to the claimed hydrophobic acrylic polymer, Miranda *et al.* teaches at least 50% butyl acrylate which renders the polymer hydrophilic. It was also said to be obvious to select ethanol to achieve a dry composition because it is volatile.

In response to applicants' argument that Miranda *et al.* provides no motivation to select ethanol, such motivation is said to be provided. The Examiner thus notes that for independent claims 67 and 85 "substantially free of low volatility solvents" can include as much as 49% of such solvents, and that applicants do not define "substantially free." This rejection is respectfully traversed in view of the

above amendments and arguments and for the reasons set forth hereinafter.

Returning to the basic nature of the present invention, applicants have emphasized from the outset the fact that, in accordance with the present invention, one is able to tailor the release rate of the claimed highly plasticizing drugs, which have a low molecular weight and are liquid at or about room temperature. In addition, one can also tailor their permeation rate through the skin, by dealing with the overall nature of these transdermal systems, and the solvent utilized therein, and by not focusing solely upon the specific adhesive utilized therein. Thus, in accordance with the present claims, the only solvents used in producing therapeutic adhesive formulations including a highly plasticizing drug are relatively high volatility solvents, such as ethanol, which are readily removed upon drying. Less volatile solvents such as propylene glycol, however, which remain in these systems even after drying at the temperatures in the claims, as is discussed in the specification at ¶[0026], are now specifically excluded from the presently claimed adhesive formulations. Once again, since Miranda *et al.* specifically teaches one to utilize such solvents, it is abundantly clear that this reference cannot at the same time be said to somehow teach one to exclude these solvents, as required by these claims. Amended claims 67 and 85 now clearly exclude low volatility solvents, such as propylene glycol, which would not be driven off during drying at temperatures of from 100°F to 200°F. Miranda *et al.* thus clearly teaches away from the present invention, and the entire basis for the Examiner's rejection based on Miranda *et al.* is now believed to be insupportable.

As applicants have previously pointed out, Miranda *et al.* does not suggest the requirement of the presently claimed invention that at least one solvent be present, but that it

explicitly cannot be a solvent having the low volatility at the specific temperatures set forth therein, such as propylene glycol. To the contrary, Miranda *et al.* teaches either a system with no solvent at all, or a system with the solvents set forth at column 13 thereof, including propylene glycol. It is thus clear that Miranda *et al.* does not teach, suggest or disclose the presently claimed invention, including the solvent system required by these claims. Applicants have also previously pointed out that claim 67 is not limited to acrylic polymers but covers a broader class of polymer systems. It was thus noted that, when Miranda *et al.* discloses an embodiment in which plasticizing drugs are used which might not require any solvents at all, the failure of the teachings in Miranda *et al.* regarding the present invention become even more apparent. Thus, when utilizing systems other than acrylate polymer systems, it might well be necessary to include solvents such as those disclosed and claimed in the present application in connection with those drugs. Miranda *et al.* clearly fails to recognize this fact by teaching that one should either utilize no solvents at all, or co-solvents including propylene glycol, which are excluded from the present claims and whose presence would clearly prevent one from realizing the results obtainable herewith.

Claims 67, 70-76, and 70-94 have been rejected as being unpatentable over Wolter *et al.* under 35 U.S.C. § 103(a). The Examiner contends that Wolter *et al.* teaches a transdermal comprising an adhesive, a drug or salt, and when a salt is present, an element containing basic groups. Selegiline is said to be disclosed, along with ethyl acetate, and DUROTAK 2516 is said to be specified as is disclosed in applicants' specification in Table III as an acrylate polymer comprising ethylhexyl acrylate and methyl acrylate crosslinked with aluminum. The Examiner thus concludes that it would be obvious to make a composition comprising selegiline and an acrylate

polymer to achieve the beneficial effect of transdermals in view of Wolter *et al.* It was said to be obvious to select ethanol to achieve a dry composition because it is volatile, and as to the claimed percent ranges of an acrylate polymer, non-aqueous solvent and drug, Wolter *et al.* is said to teach suitable amounts. Without a showing of criticality, optimum suitable amounts were said to be obtained by routine experimentation. In response to applicants' argument that element b in Wolter *et al.* contains low volatile solvents, the Examiner contends that such solvents are optional. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

It is first noted that the teachings of Wolter *et al.* are very similar to those of Miranda *et al.* Once again, reference to propylene glycol clearly negates the validity of attempting to rely on Wolter *et al.* in the first instance. Irrespective of that clear distinction, and turning to the overall disclosure in Wolter *et al.*, applicants have previously pointed out that this reference specifically discloses that when a salt of the drug is utilized, the ability for it to diffuse may be improved by concomitant use of a conventional solubilizer "such as glycerol 1,2-propanediol, the monomethyl or monoethyl ether of diethylene glycol, 2-octyldodecanol, the laurate, palmitate, stearate or oleate of sorbitol, C_8/C_{10} ethoxylated glycerides, and ethoxylated oleic glycerides." (*See* col.2 ll.54-58.) Applicants have thus previously stressed, particularly with respect to claims such as claim 67, that this patentee not only fails to disclose compositions which are free of low volatility solvents which are not driven off during drying at from 100 to 200°F, but, to the contrary, actually requires that such solvents be incorporated into their system. At this point, however, in view of the amendments to claims such as claim 67, in which it is now not only required that at least

one solvent be present, but that the solvent system thereof nevertheless be free of any of these low-volatility solvents, including compounds such as propylene glycol, it is clear that the "optional" nature of the teaching in Wolter *et al.* does not result in the claimed product. Thus, with these optional solvents, either they are not present at all, in which case the use of the solvent system required by these claims is not suggested, or the solvents are present, but they include the low-volatility solvents which are excluded from these claims. Furthermore, when Wolter *et al.*, at column 3 thereof, describes his second layer (b), applicants once again urge that this composition includes compounds which would not meet the limitations of the present claims, including the very same nonvolatile solvents which are specifically excluded by the present claim language. It is, therefore, respectfully submitted that all of these claims are clearly patentably distinguishable over this reference, and reconsideration and allowance of these claims is respectfully solicited.

Finally, claims 67, 69-76, 78-111, and 113-119 have been rejected on the basis of obviousness-type double patenting over claims 1-10 and 1-17 of U.S. Patent Nos. 7,070,808 and 7,150,881, respectively. Applicants, however, have now dealt with this rejection by filing appropriate terminal disclaimers, which clearly obviate this rejection.

It is therefore respectfully submitted that all of the claims in this application are now in condition for allowance, and reconsideration and allowance of these claims is therefore respectfully solicited.

Once again, however, if the Examiner for any reason does not agree with this position, respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Finally, if there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By_____

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